

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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TALECRIS BIOTHERAPEUTICS, INC., )

Plaintiff, )

v. )

BAXTER INTERNATIONAL INC., and )  
BAXTER HEALTHCARE CORPORATION, )

Defendants. )

BAXTER HEALTHCARE CORPORATION )

Counterclaimant, )

v. )

TALECRIS BIOTHERAPEUTICS, INC., and )  
BAYER HEALTHCARE LLC, )

Counterdefendants. )

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C.A. No. 05-349-GMS

Demand for Jury Trial

**JOINT STATUS REPORT**

Plaintiff and Counterdefendant Talecris Biotherapeutics, Inc. (hereinafter "Talecris" or "Plaintiff"), Defendant and Counterclaimant Baxter International Inc., Defendant Baxter Healthcare Corporation (hereinafter collectively "Baxter" or "Defendants") and Counterdefendant Bayer Healthcare LLC (hereinafter "Bayer") submit this Joint Report in preparation for the Status and Scheduling Conference before this Court set for March 28, 2006, at 2 p.m., pursuant to Rule 16 of the Federal Rules of Civil Procedure and Local Rule 16.2(b).

1. **Jurisdiction and Service.** The parties agree that the Court has subject matter jurisdiction over this action and that the Court has personal jurisdiction over Talecris, Bayer and Baxter. At the present time, Talecris, Bayer and Baxter believe that all necessary parties have been served and have appeared, but reserve their rights to join additional parties within the time limit agreed to in section 7 of this report.

2. **Substance of the Action.** This action arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* The patent in suit is United States Patent No. 6,686,191 (“the ‘191 patent”) which is assigned to Bayer. Talecris alleges that it is the exclusive licensee. The ‘191 patent claims: (1) a method for treating a solution of antibodies which may have virus activity; and (2) intravenously injectable immune globulins produced by such method.

Talecris and Bayer allege that Baxter is infringing the ‘191 patent in the manufacture of its liquid immune globulin drug product for intravenous administration sold under the tradename GAMMAGARD® Liquid. On April 27, 2005, the United States Food and Drug Administration (“FDA”) approved the Defendants’ Biologics License Application (“BLA”) for manufacture of GAMMAGARD® Liquid in Belgium and importation and sale of GAMMAGARD® Liquid in the United States. On or about September 26, 2005, Baxter began selling GAMMAGUARD® Liquid in the United States. Specifically, plaintiff alleges that Baxter infringes the ‘191 patent by importing GAMMAGARD® Liquid into the United States and selling, offering for sale, or using GAMMAGARD® Liquid within the United States. Plaintiff further alleges that Baxter International Inc. induced or will induce infringement by Baxter Healthcare Corporation, or *vice versa*.

Among other things, Baxter alleges Talecris is barred from obtaining any relief sought because Baxter has not infringed and is not infringing, literally or equivalently, either directly or

indirectly, any valid and enforceable claim of the '191 patent. Baxter also alleges Talecris is barred from obtaining any relief sought in the Complaint because the '191 patent, and each claim thereof, is invalid for failing to meet one or more of the conditions of patentability specified in 35 U.S.C. §§ 102, 103 and/or 112. Baxter further alleges Talecris is barred from obtaining any relief sought in the Complaint by the doctrine of prosecution history estoppel, and Talecris is estopped from claiming that the '191 patent covers or includes GAMMAGARD® Liquid. In addition, Baxter alleges Talecris is barred from obtaining any relief sought in the Complaint as it lacks standing because Bayer Healthcare LLC, the apparent owner of the '191 patent, did not join in filing this lawsuit.

By way of its counterclaim against Talecris and Bayer, Baxter Healthcare Corporation alleges that Bayer Healthcare LLC is the assignee and owner of the '191 patent. Baxter Healthcare Corporation also alleges an actual controversy has arisen and now exists between Baxter Healthcare Corporation on the one hand and Talecris and Bayer on the other hand with respect to Baxter Healthcare Corporation's noninfringement of any valid claims of the '191 patent. Baxter Healthcare Corporation contends it does not infringe any valid claim of the '191 patent. Baxter Healthcare Corporation also alleges an actual controversy has arisen and now exists between Baxter Healthcare Corporation on the one hand and Talecris and Bayer on the other hand with respect to the invalidity of the '191 patent. Baxter Healthcare Corporation contends the '191 patent is invalid for failure to meet one or more of the conditions of patentability specified in 35 U.S.C. §§ 102, 103 and/or 112.

3. **Identification of Issues.** The issues in dispute are: (a) whether the use, offer to sell, sale, and/or importation into the United States of GAMMAGARD® Liquid by Baxter has infringed, infringes, or will infringe the '191 patent; (b) whether Baxter International Inc. and/or

Baxter Healthcare Corporation has induced or will induce infringement of the '191 patent; and (c) whether the '191 patent is invalid for failure to meet one or more of the conditions of patentability specified in 35 U.S.C. §§ 102, 103 and/or 112.

4. **Narrowing of Issues.** The parties have not identified any opportunities for narrowing the issues at this time.

5. **Relief.** Talecris and Bayer seek: (a) a declaration that Baxter's GAMMAGARD® Liquid is made according to processes claimed in the '191 patent and that the use, sale, offer for sale or importation of GAMMAGARD® Liquid infringes or will infringe, literally or under the doctrine of equivalents, one or more claims of the '191 patent; (b) a judgment permanently enjoining Baxter from using, selling, offering for sale and importing GAMMAGARD® Liquid prior to expiration of the '191 patent; (c) a judgment permanently enjoining Baxter from inducing infringement of the '191 patent prior to expiration of the '191 patent; (d) attorneys' fees pursuant to 35 U.S.C. § 285; (e) costs and expenses in this action; and (f) such other relief as the Court may deem just and proper.

Baxter seeks: (a) a judgment holding Talecris takes nothing by way of its Complaint; (b) a judgment holding that Baxter Healthcare Corporation's GAMMAGARD® Liquid does not infringe, either literally or under the doctrine of equivalents, either directly or indirectly, any valid claim of the '191 patent; (c) a judgment declaring that Baxter Healthcare Corporation's GAMMAGARD® Liquid does not infringe, either literally or under the doctrine of equivalents, either directly or indirectly, any valid claim of the '191 patent; (d) a judgment declaring the claims of the '191 patent are invalid; (e) a judgment finding this case be decreed an "exceptional case" within the meaning of 35 U.S.C. § 285 and reasonable attorney fees be awarded to Baxter;

and (f) a judgment awarding such other costs and further relief as the Court deems just and proper.

6. **Amendment of Pleadings.** The parties propose that amendment of pleadings without leave of court must occur by May 5, 2006.

7. **Joinder of Parties.** The parties propose that joinder of all parties must occur by May 5, 2006.

8. **Discovery.** The parties agree that discovery generally proceed in accordance with the Federal Rules of Civil Procedure and the Local Rules of this Court. The parties propose that each side have 160 hours to depose fact witnesses, including Rule 30(b)(6) depositions.

Baxter also proposes that up to three fact (individual) witnesses per side may be noticed to be deposed for up to two 7-hour days, and that all other fact (individual) witnesses may be noticed to be deposed for up to one 7-hour day. Talecris believes that Baxter's proposal regarding the two 7-hour day depositions of three fact (individual) witnesses is premature, and will stipulate to extend a fact witness deposition beyond the seven hour limit for good cause shown.

The parties agree that each side may take up to 160 hours of expert witness depositions. Each expert witness may be deposed for up to two 7-hour days.

With the exception of the deadlines for the Amendment of Pleadings and Joinder of Parties the parties were unable to agree on a discovery schedule and hereby submit the following competing proposals:

Event	Talecris and Bayer Proposal	Baxter Proposal
<b>Fact Discovery</b>		
Exchange of Initial Disclosures	April 7, 2006	Five days after submission of Scheduling Order
Motion to Amend Pleadings	May 5, 2006	May 5, 2006
Motion to Join Additional Parties	May 5, 2006	May 5, 2006
Notice of Reliance on Advice of Counsel as a Defense to Willful Infringement	September 15, 2006	September 1, 2006
Production of Opinions of Counsel, and Production of all Related Materials	September 15, 2006	September 1, 2006
Completion of Fact Discovery	January 15, 2007	September 29, 2006
<b>Markman Proceedings</b>		
Exchange of claim terms to be construed and proposed constructions	January 15, 2007	September 29, 2006
Deadline for parties to meet and confer regarding narrowing and reducing the number of claim construction issues	January 22, 2007	October 6, 2006
Submission of Joint Claim Construction Chart	February 5, 2007	October 13, 2006
Markman Briefs	Opening: 3/05/07 Response: 3/26/07	Opening: 10/27/06 Response: 11/17/06
Markman Hearing	May 21, 2007	December 8, 2006
<b>Expert Discovery</b>		
Opening Expert Reports (burden of proof)	February 5, 2007	January 10, 2007
Answering Expert Reports	March 5, 2007	January 31, 2007
Reply Expert Reports	March 26, 2007	none, not necessary
Completion of Expert Discovery	May 7, 2007	February 23, 2007
<b>Dispositive Motions</b>		
Letter Briefs Seeking Permission	Opening: 6/11/07 Response: 6/25/07 Reply: 7/2/07	Opening: 02/01/07 Response: 02/08/07 Reply: 02/12/07
Submission of Joint Agenda Identifying Daubert Issues	June 29, 2007	February 12, 2007
Hearing Concerning Permission to File Summary Judgment Motions	July 16, 2007	February 23, 2007
Hearing to Discuss <i>Daubert</i> Issues	July 16, 2007	February 23, 2007
Summary Judgment Briefing (if permitted)	Opening: 8/6/07 Response: 9/4/07 Reply: 9/18/07	Opening: 03/12/07 Response: 04/02/07 Reply: 04/16/07
Summary Judgment Hearing	At Court's Discretion	At Court's Discretion
<b>Trial Phase</b>		
Motions <i>in limine</i>	Opening: 8/22/07 Response: 9/5/07	Opening: 05/11/07 Response: 05/25/07

Event	Talecris and Bayer Proposal	Baxter Proposal
	Reply: 9/12/07	Reply: 06/01/07
Plaintiff's Draft re: Joint Proposed Pretrial Order	August 29, 2007	May 18, 2007
Submission of Joint Proposed Pretrial Order	September 12, 2007	June 1, 2007
Pretrial Conference	October, 2007	June 29, 2007
Trial	Oct./Nov. 2007	July 2007

9. **Estimated Trial Length.** The parties estimate 10 days for this action to be tried.

Baxter intends to file a motion to bifurcate for trial the issues of willful infringement and damages from liability. At the present time, the parties have not identified any specific means of reducing the length of trial or expediting the presentation of evidence.

10. **Jury Trial.** Talecris and Bayer have demanded a jury trial.

11. **Settlement.** The parties engaged in settlement discussions on September 29, 2005, but were unable to reach a settlement. Talecris and Bayer believe that referring this case to Magistrate Judge Thyng for mediation or any other ADR mechanism is premature at this time. Baxter would welcome Magistrate Judge Thyng's participation in mediation at any time.

12. **Other Matters.** There are no other matters relating to the just, speedy and inexpensive determination of this action that counsel for the parties wish to confer about or raise with the Court at this time.

13. **Confirmation of Rule 26(f) Teleconference.** Counsel for Talecris, Bayer and Baxter have conferred regarding each of the topics listed above. Should the Court have any questions regarding the information set forth above, counsel for both parties are prepared to provide the additional information needed to address the Court's concerns.



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